510(k) Summary

AUG 07 2009

Device trade name:	Sherlock 3CG™ Tip Positioning System Sensor Sherlock 3CG™ Tip Positioning System Stylet
Device class and panel:	Class II, 21 CFR §880.5970 LJS - Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheters
Applicant name:	Rick Gaykowski Bard Access Systems, Inc. [wholly owned subsidiary of C.R. Bard, Inc.] 605 North 5600 West, Salt Lake City, UT 84116 (801) 522-0700, x5432
Predicate devices:	K061240 - Sherlock™ II Tip Location System Detector K063240 - Sherlock™ Tip Location System Stylet K081626 - FlowPICC™ Console K081625 - FlowPICC™ Stylet
Performance Standards:	Performance standards have not been established by the FDA under §514 of the Federal Food, Drug and Cosmetic Act.
Indications for Use:	*Sherlock 3CG™ Tip Positioning System Sensor:* The Sherlock 3CG™ Tip Positioning System (TPS) is indicated for central venous catheter guidance and positioning during catheter placement. The Sherlock 3CG™ TPS provides real time catheter tip location information through the use of passive magnet and cardiac electrical signal detection. *Sherlock 3CG™ Tip Positioning System Stylet:* Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG™ Tip Positioning System (TPS), the Sherlock 3CG™ TPS stylet also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.
Device description:	The Sherlock 3CG™ Tip Positioning System (TPS) consists of a sensor, stylet, and connection assembly. The system is designed to aid in central venous catheter tip positioning through magnet tracking and ECG signal information. The Sherlock 3CG™ TPS System detects and displays the position of the magnet-tipped stylet relative to the sensor. In addition, the Sherlock 3CG™ TPS System detects and displays a cardiac electrical signal from the three ECG electrodes, including the Sherlock 3CG™ TPS Stylet and two body electrodes, which provide catheter tip positioning information.
Technological Characteristics:	Technological similarities between the subject Sherlock 3CG™ Tip Positioning System Sensor and Sherlock 3CG™ Tip Positioning System Stylet and the predicate devices remain identical. There are no new questions raised regarding safety or efficacy of these devices.
Safety & Performance Tests:	Verification and validation tests have been performed in accordance with Design Controls per 21 CFR §820.30.
Summary of Substantial Equivalence:	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Sherlock 3CG™ TPS System, consisting of the Sherlock 3CG™ TPS Sensor and Sherlock 3CG™ TPS Stylet met the minimum requirements that are considered adequate for its intended use and are substantially equivalent in design, materials, sterilization, principles of operation and indications for use to the current commercially available Sherlock™ II Tip Location System, which consists of the Sherlock™ II Tip Location System Detector and Sherlock™ Tip Location System Stylet; and the FlowPICC™ System, which consists of the FlowPICC™ Console and FlowPICC™ Stylet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Rick Gaykowski
Vice President, Regulatory Affairs
Bard Access Systems, Incorporated
C.R. Bard, Incorporated
605 North 5600 West
Salt Lake, Utah 84116

AUG 0 7 2009

Re: K091324
Trade/Device Name: Sherlock 3CG™ Tip Positioning System Stylet, Sherlock 3CG™ Tip Positioning System Sensor
Regulation Number: 880.5970
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 6, 2006
Received: July 8, 2009

Dear Mr. Gaykowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Sherlock 3CG™ Tip Positioning System Stylet

Indications for Use:

Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG™ Tip Positioning System (TPS), the Sherlock 3CG™ TPS Stylet also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091324

510(k) Number (if known): _____

Device Name: Sherlock 3CG™ Tip Positioning System Sensor

Indications for Use:

The Sherlock 3CG™ Tip Positioning System (TPS) is indicated for central venous catheter guidance and positioning during catheter placement. The Sherlock 3CG™ TPS provides real time catheter tip location information through the use of passive magnet and cardiac electrical signal detection.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091324